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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,322	08/22/2001	Phuong Grace Dang	452005-13	1448

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/935,322

Applicant(s)

DANG ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other:

### DETAILED ACTION

Amendment A and Supplementary IDS received on November 25, 2002 are acknowledged. Claims 1-14 are included in the prosecution of this application.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sims et al (5164398).**

Sims et al teach a pharmaceutical composition containing an analgesic, an antitussive, and expectorant for the relief of cough and cold symptoms (co. 1, lines 30-65). Sims teaches carbetapentane or its salt including tannate as the antitussive agent (col. 2, line 39). Guaifenesin is taught as one of the expectorants that can be used. The antitussive agent is used is 1mg to 50mg and the expectorant is used between 100mg to 100mg (col.3, lines 30-40). Sims teaches the composition in the form of a tablet or suspension (col. 3, lines 40-41).

Sims et al do not exemplify a composition containing guaifenesin and carbetapentane tannate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine guaifenesin and carbetapentane in a cold relief composition. One would be motivated to do so with a reasonable expectation of a

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similar cough and cold relief since Sims suggests instant combination and teaches the suitable dosage ranges.

### ***Response to Arguments***

Applicant argues that Sims does not exemplify any composition containing guaifenesin or carbetapentane or a combination of both. The applicant argues that Sims is directed to ibuprofen and an antitussive and one of ordinary skill in the art would not abandon ibuprofen.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the rejection is made in an obviousness-type rejection and in such as rejection the invention does not need to be exemplified as seen in an anticipatory reference, the art merely needs to suggest the invention as seen in Sims et al. The examiner points to column 1, lines 30-46 where Sims teaches an analgesic, an antitussive, and an expectorant. Although the reference provides for the "optional" use of an expectorant, Sims clearly envisions the use of both agents as seen throughout the patent and claim 5 in which guaifenesin is incorporated into the ibuprofen-antitussive composition. Further, the antitussive is selected from a Markush group of five and the expectorant is selected from a group of four. In the absence of unexpected results, it is the examiner's position that the possible combinations set forth by the prior art are not unreasonable to one of ordinary skill and are envisioned. Secondly, the claim language "composition comprising pharmaceutically effective amounts of active ingredients" does not exclude the incorporation of ibuprofen. The examiner notes the use of "consisting language"; however this only denotes that carbetapentane tannate and guaifenesin are

required in the composition, which is suggested by Sims as discussed above. Lastly, the omission of an element and its function is obvious if the function of the element is not desired (*Note MPEP 2144.04*). In instant case, the instant invention teaches an antitussive and expectorant composition for the relief of cough and cold. Sims et al teaches a composition for the treatment of pain and inflammation due to cough and cold wherein the antitussive agent acts as a cough suppressant and the expectorants relieves congestion. Therefore, the omission of the analgesic would still render a composition that relieves cough and cold symptoms due to the antitussive and expectorant agents and as required by instant invention.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG  
~~KHH~~

January 28, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER